UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

INNA DESCH,

Plaintiff,

v.

ULTHERA, INC. and MERZ NORTH AMERICA, INC.,

Defendants.

MEMORANDUM & ORDER
22-CV-02688 (HG)

Plaintiff has asserted various products liability and other common law claims related to her use of Defendants' medical device that the parties have referred to alternatively as the "Ulthera system" and the "Ultherapy [s]ystem." *See* ECF No. 17 at ¶¶ 3–7, 131–232; ECF No. 18-1 at 1. Defendants have filed a motion to dismiss Plaintiff's Amended Complaint in its entirety, *see* ECF No. 18, and included a placeholder document as one of the exhibits in support of their motion, *see* ECF No. 18-4. The placeholder document corresponds to a petition that Defendants submitted to the U.S. Food and Drug Administration ("FDA") in 2007 seeking permission to market the Ulthera system. *See* ECF No. 18-3 ¶ 5. Defendants filed concurrently with their motion to dismiss a motion seeking permission to file under seal an excerpted version of that FDA petition, and Defendants' motion to seal included a proposed copy of those excerpts for the Court's consideration. *See* ECF Nos. 19, 19-2. For the reasons described below, the Court finds that Defendants' proposed exhibit is unnecessary to decide Defendants' motion to dismiss and therefore denies Defendants' motion to seal and instead strikes Defendants' proposed exhibit from the docket. The Court will not rely on the excerpts of Defendants' FDA petition in any future decision on Defendants' motion to dismiss Plaintiff's Amended Complaint.

To determine whether Defendants may file under seal excerpts of their FDA petition, the Court must first determine whether the petition is a "judicial document[]" "subject to a presumptive right of public access, whether on common law or First Amendment grounds." *United States v. HSBC Bank USA, N.A.*, 863 F.3d 125, 134 (2d Cir. 2017). If the petition is a judicial document, then the Court "must determine the weight of that presumption" of access and "balance competing considerations against it" such as "the privacy interests of those resisting disclosure." *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 119–20 (2d Cir. 2006) (internal quotation marks and citations omitted).

Defendants seek to file excerpts of their FDA petition to support their motion to dismiss Plaintiff's Amended Complaint in its entirety. "Court filings in connection with a motion to dismiss are . . . judicial documents, and are generally entitled to a strong presumption of public access." *Alcon Vision, LLC v. Lens.com*, No. 18-cv-0407, 2020 WL 3791865, at *6 (E.D.N.Y. July 7, 2020) (internal quotation marks and citations omitted); *see also Brown v. Maxwell*, 929 F.3d 41, 50 (2d Cir. 2019) (explaining that "compelling" reasons are required to seal documents filed "in connection with dispositive motions such as motions for dismissal or summary judgment"). A document that contains trade secrets or other "highly competitive business information" may typically be filed under seal at least in part. *P&L Dev., LLC v. Gerber Prods. Co.*, No. 21-cv-5382, 2022 WL 1441999, at *3 (E.D.N.Y. May 6, 2022). Defendants assert that their FDA petition satisfies this criteria because, at the time the petition was submitted to the FDA, it was designated as exempt from the FDA's disclosure obligations under the Freedom of Information Act. *See* ECF No. 19 at 2 (citing 21 § C.F.R. 20.61). However, "judicial precedent does not afford blanket protection against disclosure of communications with the FDA" even if those communications have been designated as confidential and not been made public. *King*

Pharms., Inc. v. Eon Labs, Inc., No. 04-cv-5540, 2010 WL 3924689, at *8 (E.D.N.Y. Sept. 28, 2010).

Defendants' motion to dismiss cites their FDA petition to support their argument that FDA regulations—and the FDA's corresponding approval of the Ulthera system pursuant to those regulations—preempt Plaintiff's common law claims arising under state law. *See* ECF No. 18-1 at 6–10. Specifically, Defendants cite the FDA petition as support for their assertion that Defendants' request for FDA approval of the Ulthera system included "bench testing, testing on animal and cadaver tissue, human clinical trials, and proposed labeling and instructions." *See id.* at 2; *see also id.* at 9 (explaining that the petition "included clinical trials in humans as well as draft instructions for use"). However, this same information is independently apparent from two documents that Defendants have publicly filed in support of their motion to dismiss: (i) the FDA's letter granting Defendant Ulthera, Inc. permission to market the Ulthera system, subject to the requirements of a particular FDA guidance document; and (ii) the FDA's public guidance document that specifies requirements for animal testing, clinical testing, and labeling. *See* ECF No. 18-5 at 3–4; ECF No. 18-6 at 8–12. Accordingly, the additional level of detail included in Defendants' proposed excerpt of their FDA petition is "unnecessary at this stage of the litigation," and "the exhibit[] should be stricken from the docket" rather than filed under seal. *Blatt v. City of New York*, No. 19-cv-1227, 2019 WL 1367605, at *3 (S.D.N.Y. Mar. 26, 2019); *see also Brown*, 929 F.3d at 51–52 (explaining that a court may use its "supervisory power over its own records and files" to strike from the docket records that are "redundant, immaterial, [or] impertinent" even if those records do not meet the criteria to file under seal).

For the reasons explained above, the Court denies Defendants' motion to file under seal an excerpted version of their FDA petition as an exhibit in support of their motion to dismiss

Plaintiff's Amended Complaint. The information contained in Defendants' proposed excerpt of the FDA petition is not relevant to the Court's eventual decision on Defendants' motion to dismiss. The Court has therefore struck from the docket ECF No. 19-2, which contained Defendants' proposed excerpts of the petition. The Court's decision on this motion is without prejudice to Defendants seeking to file under seal part or all of their FDA petition at a later stage of this litigation if and when the information in the petition becomes relevant.

SO ORDERED.

/s/ Hector Gonzalez
HECTOR GONZALEZ
United States District Judge

Dated: Brooklyn, New York
July 28, 2022